REMARKS

I. Status of the Claims

Claims 1, 8, 17, and 21 are currently pending. By this paper claim 1 is amended for clarity. No new matter is added by this amendment. Support for the amendment to claim 1 can be found, for example, at paragraphs 75 and 86-89 of the application as filed.

II. Rejections of the Claims under 35 U.S.C. 102(a)

Claims 1 and 17 stand rejected as allegedly being anticipated by Welch reference "CZ" as cited on form PTO-1449 filed on May 29, 2007. This reference is Welch *et al.* (2003), "Neuropeptide Treatment of Genetic and Acquired IBD and Concomitant Brain Activation in Areas Abnormal in Autism," Society for Neuroscience Abstract, Program No. 318.5, (hereinafter "Welch 2003").

Applicants submit herewith a Declaration under 37 C.F.R. § 1.131 (the "Declaration") with evidence that the subject matter of claim 1 was reduced to practice by the inventors at least prior to October 3, 2002 (the earliest possible effective date of Hollander, discussed below), and was therefore also reduced to practice prior to the publication of Welch 2003.

With regard to claim 17, directed to a kit comprising the pharmaceutical composition of claim 1, the Examiner stated "Welch teaches administration of S/OT composition (45-90 μg) iv or ip by Alzet pump. The pump constitutes a kit comprising the composition." Exhibits A and B to the Declaration show that the pharmaceutical composition of claim 1 was administered to rats using such a pump. Thus, the Declaration shows that the inventors had reduced to practice a "kit" comprising the pharmaceutical composition of claim 1 at least prior to October 3, 2002. Applicants submit that the Declaration is sufficient to overcome the rejection of claim 17. MPEP § 715.02 provides that a Declaration under 37 C.F.R. § 1.131 can overcome a rejection even if not fully commensurate with the rejected claim if the differences between the claimed subject matter and the showing under 37 C.F.R. § 1.131 would have been obvious to one of ordinary skill in the art, in view of the evidence offered. Here, applicants submit that kits comprising pharmaceutical compositions were known in the art prior to Welch 2003 such that a kit comprising the

pharmaceutical composition of claim 1 would have been obvious to one of ordinary skill in the art, in view of Applicant's 37 C.F.R. § 1.131 evidence, prior to the effective date of Welch 2003.

Thus, the Declaration under 37 C.F.R. § 1.131 submitted herewith establishes that Welch 2003 does not qualify as prior art to claims 1 or 17 within the meaning of 35 U.S.C. §102(a).

Accordingly, it is respectfully requested that the rejection of claims 1 and 17 under 35 U.S.C. § 102(a) as being anticipated by Welch 2003 be reconsidered and withdrawn.

III. Rejections Under 35 U.S.C. § 103(a)

Claims 1, 8, 17, and 21 stand rejected as allegedly being obvious over "Hollander" (U.S. Pub. 2006/0105939) in view of an "NIH News Alert" ("The Use of Secretin to Treat Autism" Internet document dated 08/17/2001), "Swain" (E. Swain, Pharmaceutical and Medical Packaging News (1999)) and "Pierce" (PIERCE Technical Resource Sheet TR0043.0 "Protein Stability and Storage" 6/03).

As described above, applicants submit herewith a Declaration under 37 C.F.R. § 1.131 (the "Declaration") providing evidence that the subject matter of claims 1 and 17 was reduced to practice by the inventors at least prior to October 3, 2002 - the earliest possible effective date of Hollander, and thus does not qualify as prior art to these claims.

Furthermore, applicants submit that the Declaration also establishes that Hollander does not qualify as prior art to claims 8 and 21. It is the Examiner's position that inclusion of a protease inhibitor in the claimed composition and/or kit, as recited in claims 8 and 21, would have been obvious (see page 6 of the Office Action). Therefore, applicants' Declaration is sufficient to establish that Hollander does not qualify as prior art to claims 8 and 21.

The Declaration under 37 C.F.R. § 1.131 submitted herewith establishes that Hollander does not qualify as prior art to claims 1, 8, 17, or 21 under 35 U.S.C. § 102(e), and therefore can not be used to reject the present claims under 35 U.S.C. § 103(a). Without the Hollander reference, the remaining three references cannot support the rejection.

Accordingly, it is respectfully requested that the rejection of claims 1, 8, 17, and 21 under 35 U.S.C. § 103(a) as being obvious over Hollander in view of the NIH News Alert, Swain, and Pierce, be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing remarks and the Declarations submitted concurrently herewith, Applicant believes that all of the Examiner's concerns have been addressed. Accordingly, Applicant respectfully requests reconsideration and allowance of the pending claims. If it will facilitate prosecution of this application, the Examiner is invited to contact the undersigned at the telephone number below.

Respectfully submitted,

Dated: July 22, 2009

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